US009415221B2

(12) **United States Patent**
Greenberg et al.

(10) **Patent No.: US 9,415,221 B2**
(45) **Date of Patent: *Aug. 16, 2016**

(54) **PACKAGE FOR AN IMPLANTABLE DEVICE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/903,805**

(22) Filed: **May 28, 2013**

(65) **Prior Publication Data**

US 2013/0268039 A1 Oct. 10, 2013

Related U.S. Application Data

(62) Division of application No. 11/385,314, filed on Mar. 20, 2006, now Pat. No. 8,473,048.

(60) Provisional application No. 60/675,980, filed on Apr. 28, 2005.

(51) **Int. Cl.**

A61N 1/18	(2006.01)
A61N 1/36	(2006.01)
A61N 1/05	(2006.01)
A61N 1/375	(2006.01)

(52) **U.S. Cl.**
CPC ***A61N 1/36046*** (2013.01); ***A61N 1/0543*** (2013.01); *A61N 1/375* (2013.01)

(58) **Field of Classification Search**
CPC A61N 1/0543; A61N 1/36046
USPC 607/54
See application file for complete search history.

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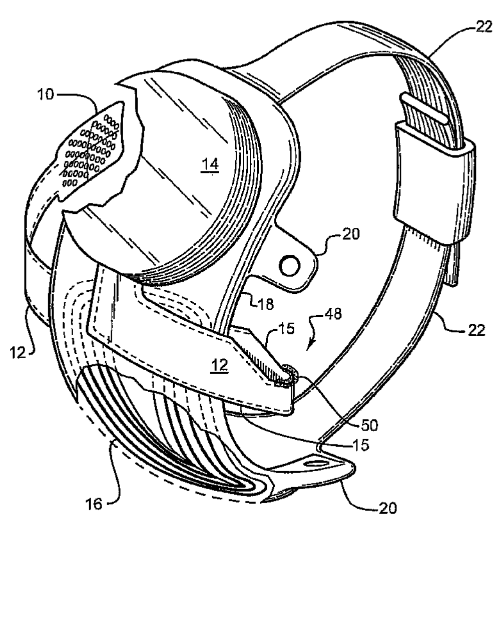
(57) **ABSTRACT**

The present invention is an improved hermetic package for implantation in the human body. The implantable device of the present invention includes an eclectically non-conductive bass including electrically conductive vias through the substrate. A circuit is flip-chip bonded to a subset of the vias. A second circuit is wire bonded to another subset of the vias. Finally, a cover is bonded to the substrate such that the cover, substrate and vias form a hermetic package.

19 Claims, 6 Drawing Sheets



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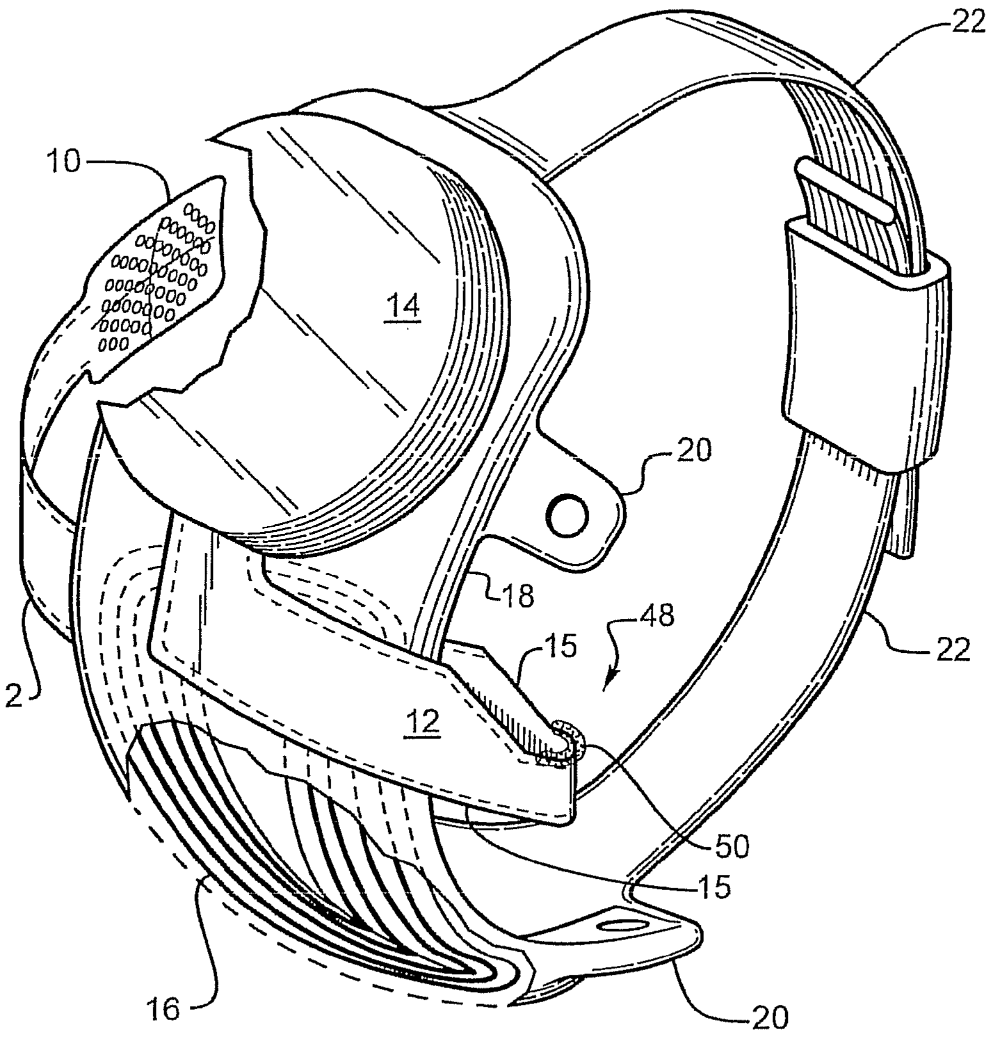

Fig. 1

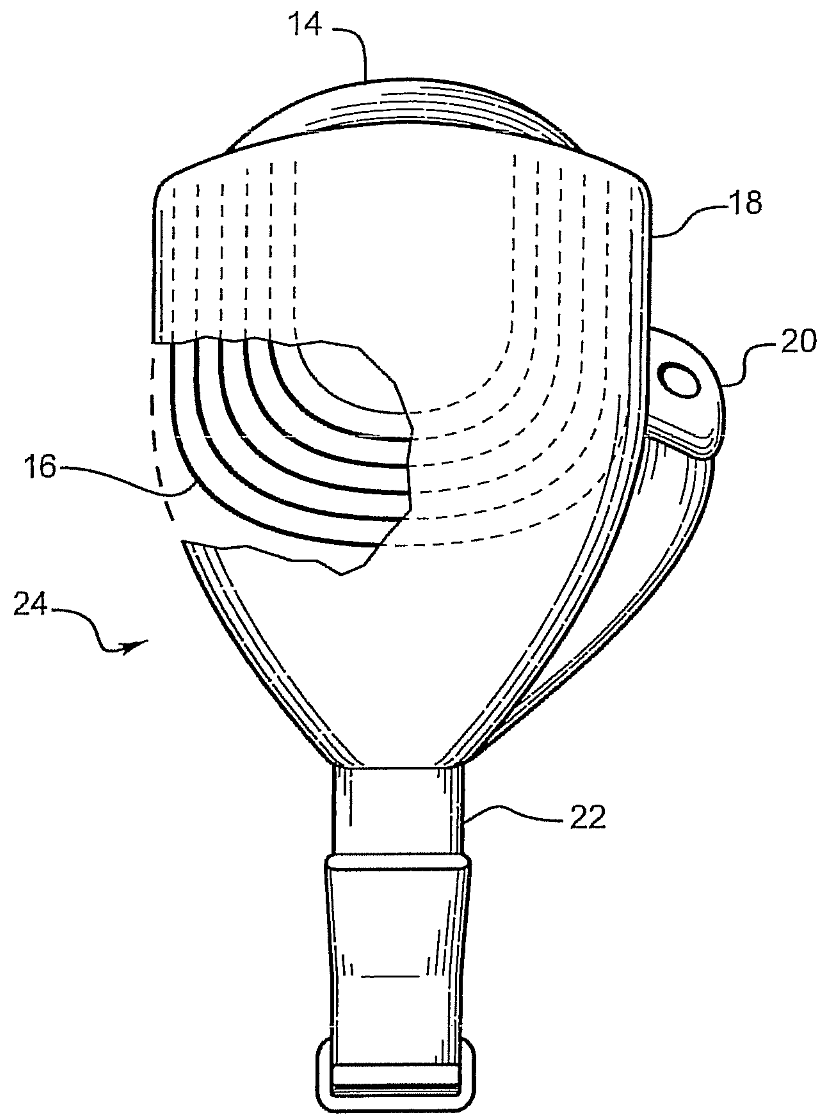

Fig. 2

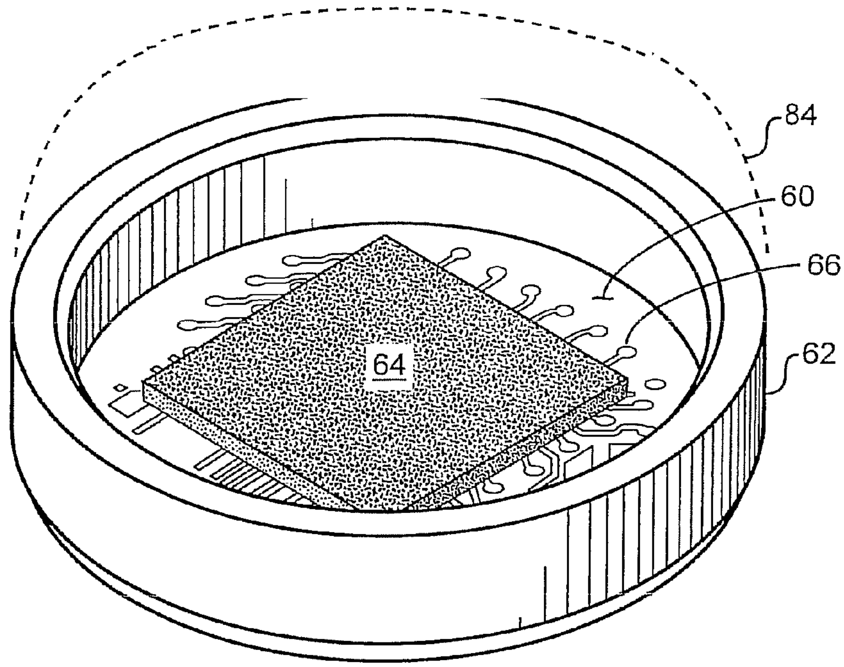

Fig. 3

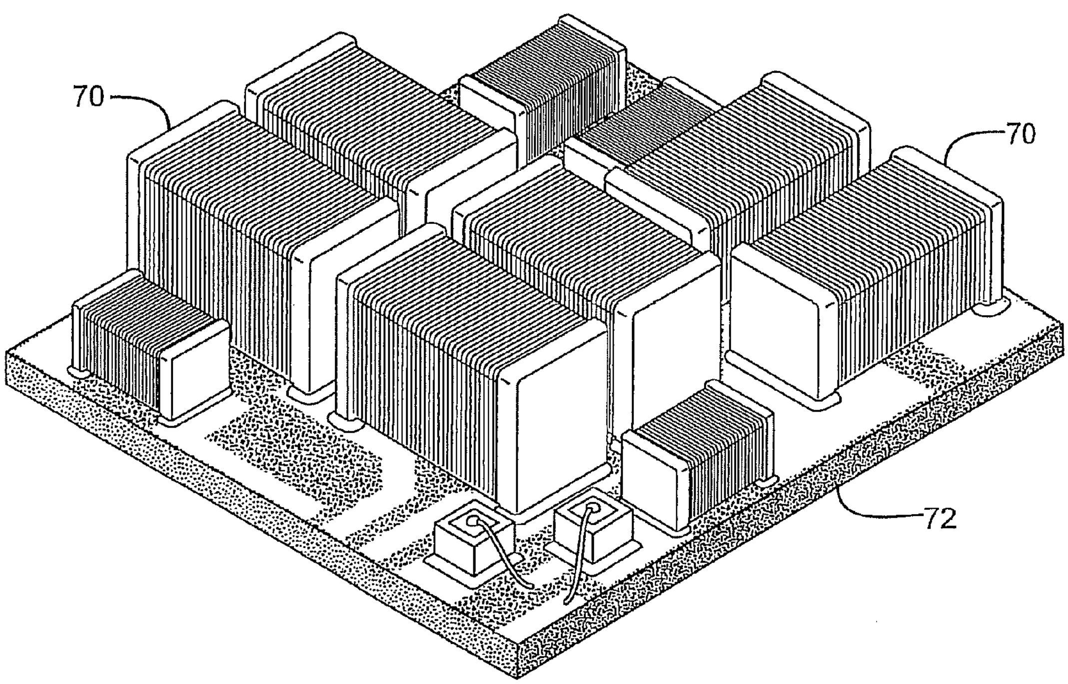

Fig. 4

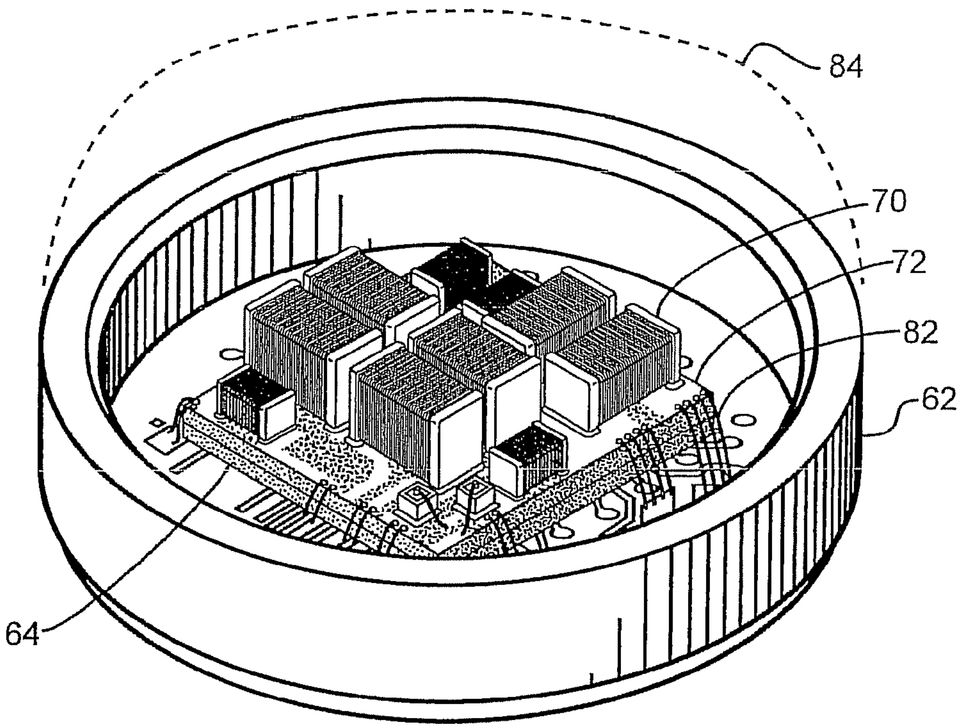

Fig. 5

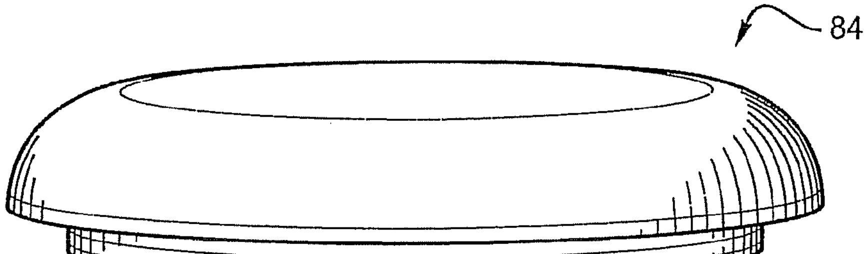

Fig. 6

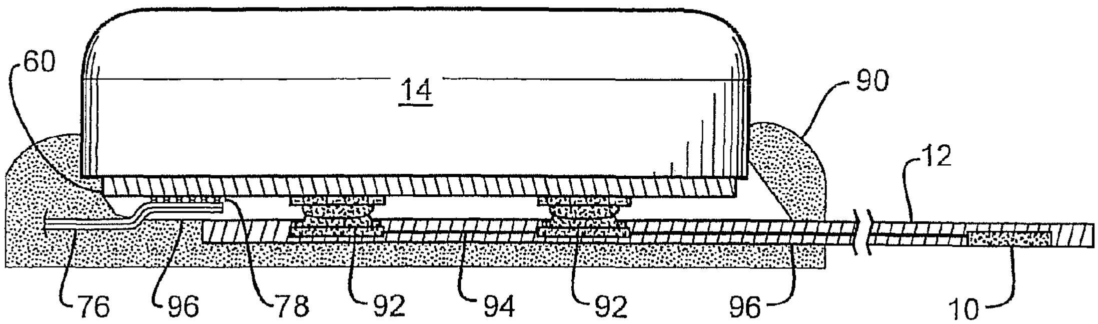

Fig. 7

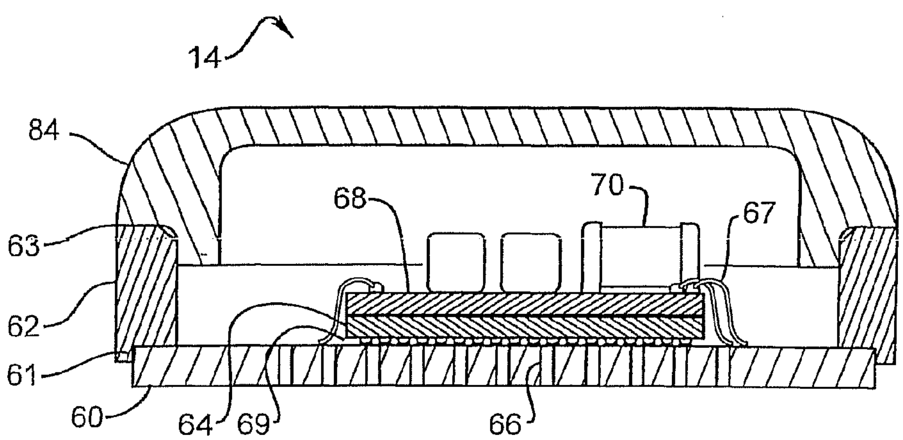

Fig. 8

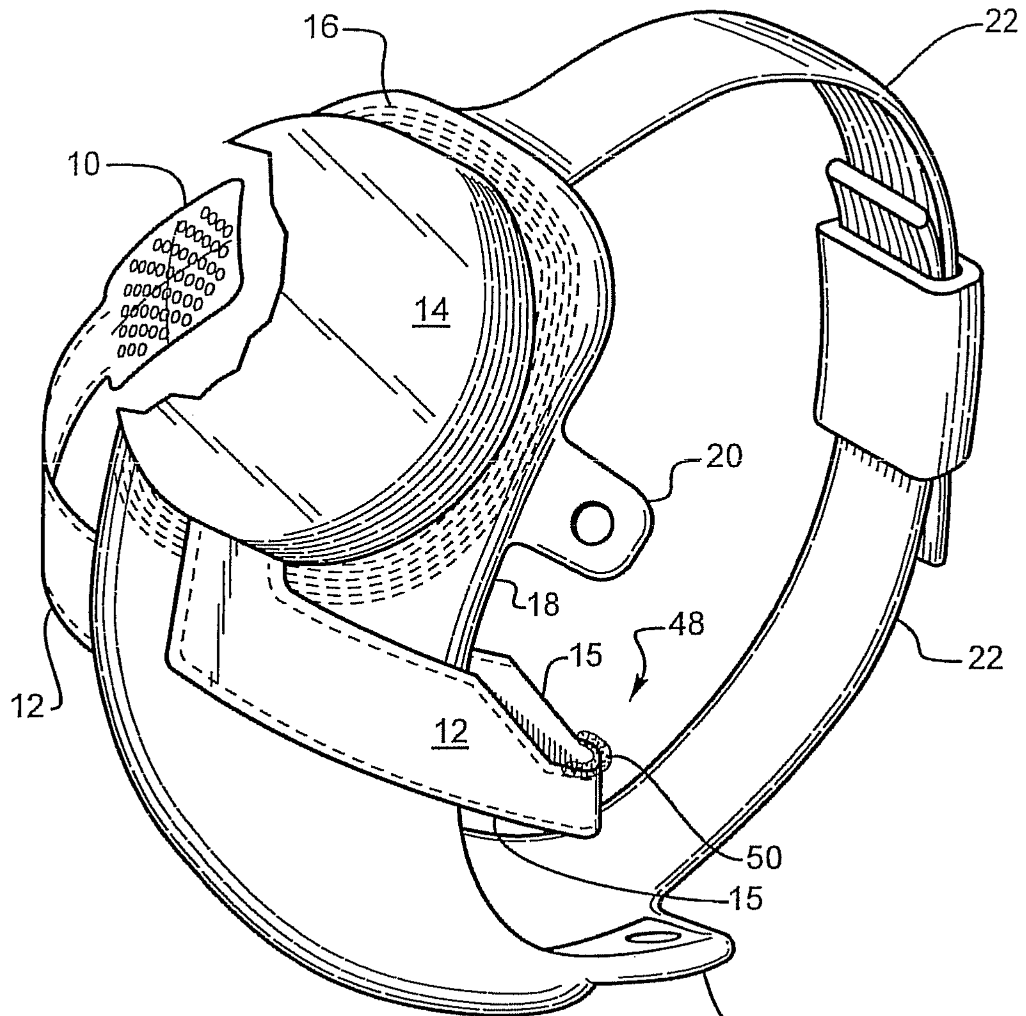

Fig. 9

PACKAGE FOR AN IMPLANTABLE DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

"This application is a divisional application of U.S. patent application Ser. No. 11/385,314 (now U.S. Pat. No. 8,473,048), filed Mar. 20, 2006, for Package for an Implantable Neural Stimulation Device", which claims benefit of U.S. Provisional Patent application Ser. No. 60/675,980, filed on Apr. 28, 2005, entitled "Implantable Chip Scale Package and Low Profile Ocular Mount," the disclosure of which is incorporated herein by reference.

This application is related to, but not dependent on, U.S. patent application Ser. No. 09/823,464 for Method and Apparatus for Providing Hermetic Feedthroughs filed Mar. 30, 2001 (now U.S. Pat. No. 7,480,988); Ser. No. 10/174,349 for Biocompatible Bonding Method and Electronics Package Suitable for Implantation filed Jun. 17, 2002 (now U.S. Pat. No. 7,211,103); Ser. No. 10/236,396 for Biocompatible Bonding Method and Electronics Package Suitable for Implantation filed Sep. 6, 2002 (now U.S. Pat. No. 7,142,909); Ser. No. 10/820,240 for Retinal Prosthesis with Side Mounted Inductive Coil filed Apr. 6, 2004 (now U.S. Pat. No. 7,228,181); Ser. No. 11/206,482 for Package for an Implantable Medical Device filed Aug. 17, 2005 (now U.S. Pat. No. 7,565,203); and Ser. No. 11/207,644 for Flexible Circuit Electrode Array filed Aug. 19, 2005 (now U.S. Pat. No. 8,014,878) all of which are assigned to a common assignee and incorporated herein by reference.

GOVERNMENT RIGHTS NOTICE

This invention was made with government support under grant No. R24EY12893-01, awarded by the National Institutes of Health. The government has certain rights in the invention.

FIELD OF THE INVENTION

The present invention is generally directed to implantable devices and more specifically to an improved hermetic package for an implantable device.

BACKGROUND OF THE INVENTION

In 1755 LeRoy passed the discharge of a Leyden jar through the orbit of a man who was blind from cataract and the patient saw "flames passing rapidly downwards." Ever since, there has been a fascination with electrically elicited visual perception. The general concept of electrical stimulation of retinal cells to produce these flashes of light or phosphenes has been known for quite some time. Based on these general principles, some early attempts at devising prostheses for aiding the visually impaired have included attaching electrodes to the head or eyelids of patients. While some of these early attempts met with some limited success, these early prosthetic devices were large, bulky and could not produce adequate simulated vision to truly aid the visually impaired.

In the early 1930's, Foerster investigated the effect of electrically stimulating the exposed occipital pole of one cerebral hemisphere. He found that, when a point at the extreme occipital pole was stimulated, the patient perceived a small spot of light directly in front and motionless (a phosphene). Subsequently, Brindley and Lewin (1968) thoroughly studied electrical stimulation of the human occipital (visual) cortex. By varying the stimulation parameters, these investigators described in detail the location of the phosphenes produced relative to the specific region of the occipital cortex stimulated. These experiments demonstrated: (1) the consistent shape and position of phosphenes; (2) that increased stimulation pulse duration made phosphenes brighter; and (3) that there was no detectable interaction between neighboring electrodes which were as close as 2.4 mm apart.

As intraocular surgical techniques have advanced, it has become possible to apply stimulation on small groups and even on individual retinal cells to generate focused phosphenes through devices implanted within the eye itself. This has sparked renewed interest in developing methods and apparati to aid the visually impaired. Specifically, great effort has been expended in the area of intraocular retinal prosthesis devices in an effort to restore vision in cases where blindness is caused by photoreceptor degenerative retinal diseases; such as retinitis pigmentosa and age related macular degeneration which affect millions of people worldwide.

Neural tissue can be artificially stimulated and activated by prosthetic devices that pass pulses of electrical current through electrodes on such a device. The passage of current causes changes in electrical potentials across visual neuronal membranes, which can initiate visual neuron action potentials, which are the means of information transfer in the nervous system.

Based on this mechanism, it is possible to input information into the nervous system by coding the sensory information as a sequence of electrical pulses which are relayed to the nervous system via the prosthetic device. In this way, it is possible to provide artificial sensations including vision.

One typical application of neural tissue stimulation is in the rehabilitation of the blind. Some forms of blindness involve selective loss of the light sensitive transducers of the retina. Other retinal neurons remain viable, however, and may be activated in the manner described above by placement of a prosthetic electrode device on the inner (toward the vitreous) retinal surface (epiretinal). This placement must be mechanically stable, minimize the distance between the device electrodes and the visual neurons, control the electronic field distribution and avoid undue compression of the visual neurons.

In 1986, Bullara (U.S. Pat. No. 4,573,481) patented an electrode assembly for surgical implantation on a nerve. The matrix was silicone with embedded iridium electrodes. The assembly fit around a nerve to stimulate it.

Dawson and Radtke stimulated cat's retina by direct electrical stimulation of the retinal ganglion cell layer. These experimenters placed nine and then fourteen electrodes upon the inner retinal layer (i.e., primarily the ganglion cell layer) of two cats. Their experiments suggested that electrical stimulation of the retina with 30 to 100 μA current resulted in visual cortical responses. These experiments were carried out with needle-shaped electrodes that penetrated the surface of the retina (see also U.S. Pat. No. 4,628,933 to Michelson).

The Michelson '933 apparatus includes an array of photosensitive devices on its surface that are connected to a plurality of electrodes positioned on the opposite surface of the device to stimulate the retina. These electrodes are disposed to form an array similar to a "bed of nails" having conductors which impinge directly on the retina to stimulate the retinal cells. U.S. Pat. No. 4,837,049 to Byers describes spike electrodes for neural stimulation. Each spike electrode pierces neural tissue for better electrical contact. U.S. Pat. No. 5,215,088 to Norman describes an array of spike electrodes for cortical stimulation. Each spike pierces cortical tissue for better electrical contact.

The art of implanting an intraocular prosthetic device to electrically stimulate the retina was advanced with the introduction of retinal tacks in retinal surgery. De Juan, et al. at Duke University Eye Center inserted retinal tacks into retinas in an effort to reattach retinas that had detached from the underlying choroid, which is the source of blood supply for the outer retina and thus the photoreceptors. See, e.g., E. de Juan, et al., 99 Am. J. Ophthalmol. 272 (1985). These retinal tacks have proved to be biocompatible and remain embedded in the retina, and choroid/sclera, effectively pinning the retina against the choroid and the posterior aspects of the globe. Retinal tacks are one way to attach a retinal electrode array to the retina. U.S. Pat. No. 5,109,844 to de Juan describes a flat electrode array placed against the retina for visual stimulation. U.S. Pat. No. 5,935,155 to Humayun describes a retinal prosthesis for use with the flat retinal array described in de Juan.

U.S. Patent Application 2003/0109903 to Berrang describes a Low profile subcutaneous enclosure, in particular and metal over ceramic hermetic package for implantation under the skin.

SUMMARY OF THE INVENTION

The present invention is an improved hermetic package for implantation in the human body. The implantable device of the present invention includes an electrically non-conductive substrate including electrically conductive vias through the substrate. A circuit is flip-chip bonded to a subset of the vias. A second circuit is wire bonded to another subset of the vias. Finally, a cover is bonded to the substrate such that the cover, substrate and vias form a hermetic package.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the implanted portion of the preferred retinal prosthesis.

FIG. **2** is a side view of the implanted portion of the preferred retinal prosthesis showing the strap fan tail in more detail.

FIG. **3** is a perspective view of a partially built package showing the substrate, chip and the package wall.

FIG. **4** is a perspective view of the hybrid stack placed on top of the chip.

FIG. **5** is a perspective view of the partially built package showing the hybrid stack placed inside.

FIG. **6** is a perspective view of the lid to be welded to the top of the package.

FIG. **7** is a view of the completed package attached to an electrode array.

FIG. **8** is a cross-section of the package.

FIG. **9** is a perspective view of the implanted portion of the preferred retinal prosthesis.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

The present invention is an improved hermetic package for implanting electronics within a body. Electronics are commonly implanted in the body for neural stimulation and other purposes. The improved package allows for miniaturization of the package which is particularly useful in a retinal or other visual prosthesis for electrical stimulation of the retina.

FIG. **1** shows a perspective view of the implanted portion of the preferred retinal prosthesis. A flexible circuit **1** includes a flexible circuit electrode array **10** which is mounted by a retinal tack (not shown) or similar means to the epiretinal surface. The flexible circuit electrode array **10** is electrically coupled by a flexible circuit cable **12**, which pierces the sclera in the pars plana region, and is electrically coupled to an electronics package **14**, external to the sclera. Further an electrode array fan tail **15** is formed of molded silicone and attaches the electrode array cable **12** to a molded body **18** to reduce possible damage from any stresses applied during implantation.

The electronics package **14** is electrically coupled to a secondary inductive coil **16**. Preferably the secondary inductive coil **16** is made from wound wire. Alternatively, the secondary inductive coil **16** may be made from a flexible circuit polymer sandwich with wire traces deposited between layers of flexible circuit polymer. The electronics package **14** and secondary inductive coil **16** are held together by the molded body **18**. The molded body **18** holds the electronics package **14** and secondary inductive coil **16** end to end. This is beneficial as it reduces the height the entire device rises above the sclera. The design of the electronic package (described below) along with a molded body **18** which holds the secondary inductive coil **16** and electronics package **14** in the end to end orientation minimizes the thickness or height above the sclera of the entire device. This is important to minimize any obstruction of natural eye movement.

The molded body **18** may also include suture tabs **20**. The molded body **18** narrows to form a strap **22** which surrounds the sclera and holds the molded body **18**, secondary inductive coil **16**, and electronics package **14** in place. The molded body **18**, suture tabs **20** and strap **22** are preferably an integrated unit made of silicone elastomer. Silicone elastomer can be formed in a pre-curved shape to match the curvature of a typical sclera. However, silicone remains flexible enough to accommodate implantation and to adapt to variations in the curvature of an individual sclera. The secondary inductive coil **16** and molded body **18** are preferably oval shaped. A strap **22** can better support an oval shaped secondary inductive coil **16**.

Further it is advantageous to provide a sleeve or coating **50** that promotes healing of the sclerotomy. Polymers such as polyimide, which may be used to form the flexible circuit cable **12** and flexible circuit electrode array **10**, are generally very smooth and do not promote a good bond between the flexible circuit cable **12** and scleral tissue. A sleeve or coating of polyester, collagen, silicone, Gore-tex or similar material would bond with scleral tissue and promote healing. In particular, a porous material will allow scleral tissue to grow into the pores promoting a good bond.

It should be noted that the entire implant is attached to and supported by the sclera. An eye moves constantly. The eye moves to scan a scene and also has a jitter motion to improve acuity. Even though such motion is useless in the blind, it often continues long after a person has lost their sight. By placing the device under the rectus muscles with the electronics package in an area of fatty tissue between the rectus muscles, eye motion does not cause any flexing which might fatigue, and eventually damage, the device.

FIG. **2** shows a side view of the implanted portion of the retinal prosthesis, in particular, emphasizing the strap fan tail **24**. When implanting the retinal prosthesis, it is necessary to pass the strap **22** under the eye muscles to surround the sclera. The secondary inductive coil **16** and molded body **18** must also follow the strap **22** under the lateral rectus muscle on the side of the sclera. The implanted portion of the retinal prosthesis is very delicate. It is easy to tear the molded body **18** or break wires in the secondary inductive coil **16** or electrode array cable **12**. In order to allow the molded body **18** to slide smoothly under the lateral rectus muscle, the molded body **18** is shaped in the form of a strap fan tail **24** on the end opposite the electronics package **14**.

Referring to FIG. **3**, the hermetic electronics package **14** is composed of a ceramic substrate **60** brazed to a metal case wall **62** which is enclosed by a laser welded metal lid **84**. The metal of the wall **62** and metal lid **84** may be any biocompatible metal such as Titanium, niobium, platinum, iridium, palladium or combinations of such metals. The ceramic substrate is preferably alumina but may include other ceramics such as zirconia. The ceramic substrate **60** includes vias (not shown) made from biocompatible metal and a ceramic binder using thick-film techniques. The biocompatible metal and ceramic binder is preferably platinum flakes in a ceramic paste or frit which is the ceramic used to make the substrate. After the vias have been filled, the substrate **60** is fired and lapped to thickness. The firing process causes the ceramic to vitrify biding the ceramic of the substrate with the ceramic of the paste forming a hermetic bond. Thin-film metallization **66** is applied to both the inside and outside surfaces of the ceramic substrate **60** and an ASIC (Application Specific Integrated Circuit) integrated circuit chip **64** is bonded to the thin film metallization on the inside of the ceramic substrate **60**.

The inside thin film metallization **66** includes a gold layer to allow electrical connection using wire bonding. The inside film metallization includes preferably two to three layers with a preferred gold top layer. The next layer to the ceramic is a titanium or tantalum or mixture or alloy thereof. The next layer is preferably palladium or platinum layer or an alloy thereof. All these metals are biocompatible. The preferred metallization includes a titanium, palladium and gold layer. Gold is a preferred top layer because it is corrosion resistant and can be cold bonded with gold wire.

The outside thin film metallization includes a titanium adhesion layer and a platinum layer for connection to platinum electrode array traces. Platinum can be substituted by palladium or palladium/platinum alloy. If gold-gold wire bonding is desired a gold top layer is applied.

The package wall **62** is brazed to the ceramic substrate **60** in a vacuum furnace using a biocompatible braze material in the braze joint. Preferably, the braze material is a nickel titanium alloy. The braze temperature is approximately 1000° Celsius. Therefore the vias and thin film metallization **66** must be selected to withstand this temperature. Also, the electronics must be installed after brazing. The chip **64** is installed inside the package using thermocompression flip-chip technology. The chip is underfilled with epoxy to avoid connection failures due to thermal mismatch or vibration.

Referring to FIGS. **4** and **5**, off-chip electrical components **70**, which may include capacitors, diodes, resistors or inductors (passives), are installed on a stack substrate **72** attached to the back of the chip **64**, and connections between the stack substrate **72** and ceramic substrate **60** are made using gold wire bonds **82**. The stack substrate **72** is attached to the chip **64** with non-conductive epoxy, and the passives **70** are attached to the stack substrate **72** with conductive epoxy.

Referring to FIG. **6**, the electronics package **14** is enclosed by a metal lid **84** that, after a vacuum bake-out to remove volatiles and moisture, is attached using laser welding. A getter (moisture absorbent material) may be added after vacuum bake-out and before laser welding of the metal lid **84**. The metal lid **84** further has a metal lip **86** to protect components from the welding process and further insure a good hermetic seal. The entire package is hermetically encased. Hermeticity of the vias, braze, and the entire package is verified throughout the manufacturing process. The cylindrical package was designed to have a low profile to minimize its impact on the eye when implanted.

The implant secondary inductive coil **16**, which provides a means of establishing the inductive link between the external video processor (not shown) and the implanted device, preferably consists of gold wire. The wire is insulated with a layer of silicone. The secondary inductive coil **16** is oval shaped. The conductive wires are wound in defined pitches and curvature shape to satisfy both the electrical functional requirements and the surgical constraints. The secondary inductive coil **16**, together with the tuning capacitors in the chip **64**, forms a parallel resonant tank that is tuned at the carrier frequency to receive both power and data.

Referring to FIG. **7**, the flexible circuit **1**, includes platinum conductors **94** insulated from each other and the external environment by a biocompatible dielectric polymer **96**, preferably polyimide. One end of the array contains exposed electrode sites that are placed in close proximity to the retinal surface **10**. The other end contains bond pads **92** that permit electrical connection to the electronics package **14**. The electronic package **14** is attached to the flexible circuit **1** using a flip-chip bumping process, and epoxy underfilled. In the flip-chip bumping process, bumps containing conductive adhesive placed on bond pads **92** and bumps containing conductive adhesive placed on the electronic package **14** are aligned and melted to build a conductive connection between the bond pads **92** and the electronic package **14**. Leads **76** for the secondary inductive coil **16** are attached to gold pads **78** on the ceramic substrate **60** using thermal compression bonding, and are then covered in epoxy. The electrode array cable **12** is laser welded to the assembly junction and underfilled with epoxy. The junction of the secondary inductive coil **16**, array **1**, and electronic package **14** are encapsulated with a silicone overmold **90** that connects them together mechanically. When assembled, the hermetic electronics package **14** sits about 3 mm away from the end of the secondary inductive coil.

Since the implant device is implanted just under the conjunctiva it is possible to irritate or even erode through the conjunctiva. Eroding through the conjunctiva leaves the body open to infection. We can do several things to lessen the likelihood of conjunctiva irritation or erosion. First, it is important to keep the over all thickness of the implant to a minimum. Even though it is advantageous to mount both the electronics package **14** and the secondary inductive coil **16** on the lateral side of the sclera, the electronics package **14** is mounted higher than, but not covering, the secondary inductive coil **16**. In other words the thickness of the secondary inductive coil **16** and electronics package should not be cumulative.

It is also advantageous to place protective material between the implant device and the conjunctiva. This is particularly important at the scleratomy, where the thin film electrode array cable **12** penetrates the sclera. The thin film electrode array cable **12** must penetrate the sclera through the pars plana, not the retina. The scleratomy is, therefore, the point where the device comes closest to the conjunctiva. The protective material can be provided as a flap attached to the implant device or a separate piece placed by the surgeon at the time of implantation. Further material over the scleratomy will promote healing and sealing of the scleratomy. Suitable materials include Dacron, Teflon (polytetraflouroethylene or PTFE), Goretex (ePTFE) Tutoplast (sterilized sclera), Mersilene (Polyester) or silicone.

Referring to FIG. **8**, the package **14** contains a ceramic substrate **60**, with metallized vias **65** and thin-film metallization **66**. The package **14** contains a metal case wall **62** which is connected to the ceramic substrate **60** by braze joint **61**. On the ceramic substrate **60** an underfill **69** is applied. On the underfill **69** an integrated circuit chip **64** is positioned. On the integrated circuit chip **64** a ceramic hybrid substrate **68** is positioned. On the ceramic hybrid substrate **68** passives **70** are placed. Wirebonds **67** are leading from the ceramic substrate **60** to the ceramic hybrid substrate **68**. A metal lid **84** is connected to the metal case wall **62** by laser welded joint **63** whereby the package **14** is sealed.

FIG. **9** shows a perspective view of the implanted portion of the preferred retinal prosthesis which is an alternative to the retinal prosthesis shown in FIG. **1**.

The electronics package **14** is electrically coupled to a secondary inductive coil **16**. Preferably the secondary inductive coil **16** is made from wound wire. Alternatively, the secondary inductive coil **16** may be made from a flexible circuit polymer sandwich with wire traces deposited between layers of flexible circuit polymer. The electronics package **14** and secondary inductive coil **16** are held together by the molded body **18**. The molded body **18** holds the electronics package **14** and secondary inductive coil **16** end to end. The secondary inductive coil **16** is placed around the electronics package **14** in the molded body **18**. The molded body **18** holds the secondary inductive coil **16** and electronics package **14** in the end to end orientation and minimizes the thickness or height above the sclera of the entire device.

Accordingly, what has been shown is an improved method making a hermetic package for implantation in a body. While the invention has been described by means of specific embodiments and applications thereof, it is understood that numerous modifications and variations could be made thereto by those skilled in the art without departing from the spirit and scope of the invention. It is therefore to be understood that within the scope of the claims, the invention may be practiced otherwise than as specifically described herein.

What we claim is:

1. A biocompatible hermetic package for an implantable retinal prosthesis, comprising:

a planar base including an electrically non-conductive substrate and a plurality of electrically conductive hermetic vias through the non-conductive substrate, and biocompatible metallization on the non-conductive substrate;

an integrated circuit bonded directly to a first side of the base with conductive bumps, wherein the integrated circuit is smaller than the base defining a bonding region on the first side of the base between the integrated circuit and the edge of the base;

a circuit element electrically connected directly to the base in the bonding region;

a cover bonded to the first side of the base, the cover and the base forming a biocompatible hermetic package; and

a polymer body, including a strap, supporting the package and including suture tabs suitable to attach the package to tissue, wherein an outside of the hermetic package, including a second side of the base opposite the first side, is biocompatible ad suitable to contact tissue.

2. The hermetic package according to claim **1**, wherein said biocompatible metallization comprises thin film metallization.

3. The hermetic package of claim **1**, wherein the electrically non-conductive substrate contains ceramic.

4. The hermetic package according to claim **3**, wherein the cover contains metal.

5. The hermetic package according to claim **3**, wherein the electrically conductive vias are a metallic and ceramic paste co-fired with the electrically non-conductive substrate to form a hermetic seal.

6. The hermetic package according to claim **3**, wherein the cover is brazed to the base.

7. The hermetic package according to claim **2**, wherein the patterned thin film metallization is a multiple layer thin film metallization and the integrated circuit and the circuit element are bonded to the patterned thin film metallization.

8. The hermetic package according to claim **7**, wherein the multiple layer thin film metallization is chosen to withstand braze temperatures.

9. The hermetic package according to claim **8**, wherein the multiple layer thin film metallization comprises more than one of the metals including titanium, tantalum, gold, palladium, platinum or layers or alloys thereof.

10. The hermetic package according to claim **1**, further comprising a flexible circuit bump bonded to the base.

11. The hermetic package according to claim **1**, further comprising

metal traces deposited on the electrically non-conductive substrate and in contact with the electrically conductive vias; and

a flexible circuit attached to the metal traces.

12. The hermetic package according to claim **11**, wherein the flexible circuit is an electrode array suitable for stimulating tissue.

13. The hermetic package according to claim **1**, further comprising a polymer underfill under the integrated circuit.

14. The hermetic package according to claim **1**, wherein the conductive bumps contain at least one conductive polymer.

15. The hermetic package according to claim **1**, wherein the conductive bumps contain at least one conductive epoxy or polyimide.

16. The hermetic package according to claim **1**, wherein conductive bumps bonding the integrated circuit to the base are filled with one or more metals like silver, platinum, iridium, titanium, platinum alloys, iridium alloys, or titanium alloys or mixtures thereof.

17. The hermetic package according to claim **16**, wherein the metal or metal alloys are in dust, flake or powder form.

18. The hermetic package according to claim **1**, further comprising a getter.

19. The hermetic package according to claim **18**, wherein the getter is placed on the inside of the cover.

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